A randomised controlled trial investigating the effect of virtual reality on labour analgesia use

Published: 15-03-2021
Last updated: 22-02-2025

The aim of this study is to investigate whether VR will decrease the request for labour analgesia. Primary outcome measure:* Request for labour analgesiaSecondary outcome measures:* Patient tolerability, feasibility and satisfaction of VR use (VR-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON54329

Source
ToetsingOnline

Brief title
DELIVR

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
contractions, Labourpain

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: financieringsaanvraag loopt via NZA;indien deze geldstroom niet wordt toegekend zullen we onderzoek ook zonder financiering

voortzetten.

Intervention

Keyword: Analgesia, Labourpain, Pain, Virtual Reality

Outcome measures

Primary outcome

The primary outcome is the reduction of request for labour analgesia.

Secondary outcome

Secondary outcomes are the effect of VR on patient satisfaction of VR use (questionnaire), patient reported outcome measures (PROM) and patient reported experience measure (PREM) as defined by international consortium for health outcome measures (ICHOM), health-technology assessment analysis (HTA).

Study description

Background summary

Labour pain is the result of many complex interactions and can be regarded as one of the most serious kinds of pain. During labour, 80-90% of the women experience pain of which 65-68% rated labour pain as severe or extremely severe. Labour pain management strategies include non-pharmacological and pharmacological interventions. Pharmacological methods for pain relief during labour include inhaled analgesia (Entonox; N2O), opioids, non-opioids drugs, local anaesthetic nerve blocks, and epidural and intrathecal injections of local anaesthetics or both. Epidural analgesia (EA) is the most effective method for pain relief during labour.
In 2019, 33% of the women in The Netherlands received EA during labour. Unintended adverse effects also accompany EA, like maternal fever, hypotension, urinary retention, motor blockade and routine EA is likely to lead to more operative deliveries. Remifentanil patient-controlled analgesia (remifentanil-PCA) has also been frequently (18%) used as pain relief during labour in The Netherlands [perined 2019]. Possible side effects of remifentanil are pruritus, nausea, hyperalgesia, desaturation, respiratory depression and apnea.
Relatively common (well-known) non-pharmacological interventions for pain

relief are continuous psychological support, alternating positions during labour, intracutaneous or subcutaneous sterile water injections, transcutaneous electrical nerve stimulation, hypnosis, biofeedback, immersion in water, aromatherapy, relaxation techniques (yoga, audio, music), acupuncture or acupressure and manual methods (massage, reflexology). An alternative, at the moment not common, non-pharmacological method is the use of virtual reality (VR).
Taking into account the safety and possible adverse effects of current pharmacological pain relief during labour, it is worth exploring VR as a non-pharmacological pain relief to avoid the possible side effects of pharmacological methods for pain relief and decrease health care costs.
VR is an upcoming technology used within healthcare, which makes use of the principle of distraction. Pain perception is strongly affected by psychological factors.
The Neuromatrix Theory of Pain states that pain is a multidimensional experience, consisting of affective, sensory and cognitive components. The perception of pain is thought to be related to the amount of attention that is given to pain stimuli.
Recently a systematic review and meta-analysis showed VR to be an effective method to reduce acute pain. There is limited evidence of the use of VR during labour. An observational study investigated the effect of music in 62 women during labour and showed a significant reduction of pain and anxiety. In the VRAIL pilot study, a preliminary randomised controlled trial, 28 women in labour were enrolled. This study showed a significant decrease in pain and anxiety during labour in the VR-group. This preliminary and scarce literature suggests that VR is a potentially effective technique for improving pain and anxiety during labour. VR can be used as a safe, non-invasive, analgesic method, without risks of drug addiction and minimal side effects.
A recent qualitative study (VIREL) investigated the experience and preference and the effect on pain intensity during labour of interactive and passive virtual reality distraction. Women experienced less pain during meditation VR use and preferred the guided meditation VR during labour.

In this study, we want to investigate the effect of meditation VR (BirthVR) on the request for labour analgesia. We hypothesize that VR will reduce the request for labour analgesia and reduce the rate of referral rate from midwifery led first line care to second line obstetrical care.

Study objective

The aim of this study is to investigate whether VR will decrease the request for labour analgesia.

Primary outcome measure:
* Request for labour analgesia

Secondary outcome measures:

* Patient tolerability, feasibility and satisfaction of VR use
(VR-questionnaire, WDEQ-A and WDEQ-B)
* Patient reported outcome measures (PROM) and patient reported experience measure (PREM) as defined by international consortium for health outcome measures (ICHOM)
* Labour complications, neonatal parameters

Study design

The study concerns a non-blinded multi centre, randomised controlled trial (RCT).
Eligible patients will be randomised to either the VR group or standard care group. In addition to the standard care, the VR group receives a VR information moment during labour and the possibility to exercise with the VR glasses and they receive VR during labour from the moment they are in active labour and use VR as much as they prefer. Our hypothesis is that using *BirthCoach VR* during labour will result in a 15% decrease in the request for labour analgesia. In general multiparous women less often receive medicinal pain relief than nulliparous women. This statement is also supported by national and local data. This difference in incidence results in a different effect size. For this reason, two separate sample sizes for multi- and nulliparous have been calculated

Intervention

BirthVR tool; a virtual reality app consisting of nature environments with a guided meditation.

Study burden and risks

VR is a new technique for labour pain reduction. We performed a qualitative study (VIREL) in 23 women during labour to explore the feasibility of VR. This study showed a reduction of pain measured on the visual analogue scale (VAS) of 19 mm after the use of VR during labour. There were no adverse events after the use of VR during labour. They can experience side-effects of VR for example dizziness or nausea.

Contacts

Public
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC

NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

* Written and orally given informed consent
* 18 years and older
* Good command of Dutch language
* Singleton pregnancy
* Nulliparous or multiparous women
* Cephalic presentation
* 35+0 weeks* gestation and beyond
* Intention for a vaginal delivery
* Delivery in the Zuyderland MC

Exclusion criteria

* Chronic pain. The pain is not due to an obstetrical problem. * Chronic use of pain medication (opioids) * Alcohol or drug abuse * Known car sickness which requires the use of medication * Epileptic insults in previous history * Psychotically episode in previous history * Claustrophobic * Visual impairment (excluding the use of glasses and/or lenses * psychotic disorder * Patients in strict isolation (MRSA) * Age <18 years * Twin pregnancy * No good command of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2021
Enrollment:	716
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	15-03-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Not approved Date:	29-03-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-01-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date:	06-06-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	26-06-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	27-06-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	04-09-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	03-05-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	03-02-2025
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76837.096.21